REMARKS

I. PROSECUTION HISTORY

The application as filed contained 37 claims. On May 4, 2001, the Applicant filed a preliminary amendment canceling claims 1-37 and adding claims 38-96. In an official communication dated October 2, 2002, claims 38-96 were subjected to a restriction requirement. In a responsive Response to Restriction Requirement filed on November 4, 2002, the Applicant elected with traverse to prosecute the invention of Group I, claims 38-52 and 71-80, directed to an isolated polynucleotide as set forth in SEQ ID NO: 1. At the time of issuance of the outstanding Office Action, claims 38-96 were pending in the application. In an Office Action dated April 29, 2003, the restriction requirement of January 29, 2003 was made final; claims 82-92 and 95-96 were withdrawn from consideration; and claims 38-81 and 93-94 were rejected variously under 35 U.S.C. §§101, 102 and 112, first paragraph. Applicant responded to that action, canceled claims 1-96, and introduced claims 97-155.

A non-final Office action was mailed on March 10, 2004, in which the Office rejected claims 97-155 on various grounds including 35 U.S.C. §§ 101, 102, and 112. After entry of the present amendment, claims 1-155 will have been canceled and claims 156 to 219 will be pending, which Applicant submits are in condition for allowance. Applicant thanks Examiner Sullivan for his interview on June 17, 2004 and discussion of the utility, written description and other rejections.

II. EXPLANATION OF AMENDMENTS TO THE CLAIMS

Support for the amendments is found throughout the specification. The current claims refer to portions of SEQ ID NOS: 1 & 2 and, in doing so, refer to portions similar to the portions recited in the canceled claims, although the present claims do recite "comprising language." As a convenience to the Examiner, Applicant provides, in the Appendix, a chart summarizing relevant nucleotide and corresponding amino acid sequences and where they are referred to in the claims. Claims 194, 196, and 197 find additional support at page 4, lines 18-21 of the specification. No new matter has been added by these amendments. Applicant reserves the right to pursue, in this or related applications, claims directed to any unclaimed subject matter whether originally claimed, later claimed, or not previously claimed.

III. THE DOUBLE PATENTING REJECTION HAS BEEN RENDERED MOOT

On page 2 of the Office action, the Office objected to claims 102 and 103 under 37 C.F.R. § 1.75 as being substantial duplicates of claims 107 and 108. Claims 102, 103, 107, and 108 having been canceled, the objection has been rendered moot and should be withdrawn.

IV. THE CLAIMS ARE IN FULL COMPLIANCE WITH 35 U.S.C. § 101

On pages 3-6 of the Office action, the Office rejected claims 97-155 under 35 U.S.C. § 101 for allegedly not being supported by either a specific and substantial utility or a well-established utility. The Office further alleged that the utility described for the claimed collectin polypeptide was not proper in view of the amino acid sequence of the polypeptide being encompassed by a scavenger receptor sequence and because the receptor had properties distinct from a collectin. Applicant respectfully traverses and requests that the rejection be withdrawn as improper for the reasons discussed herein.

A. ADDITIONAL UTILITIES DO NOT UNDERMINE THOSE ALREADY DESCRIBED IN THE SPECIFICATION

The Office has alleged that the claimed subject matter lacks utility because the amino acid sequence of the claimed polypeptide constitutes a portion of a larger polypeptide corresponding to a scavenger protein. Applicant respectfully traverses. Applicant is pursuing claims directed to the scavenger receptor in a separate application (10/203,860; See Ref. B9 of the concurrently filed IDS.). However, the scavenger receptor, and any utilities recited for the same, do not undermine the utility of the presently claimed invention. Such utilities merely add to those already described for the presently claimed invention, and when the proper standard for utility is applied, such utilities should not affect the finding of utility under 35 U.S.C. § 101.

The Office alleged that the asserted utility of the claimed subject matter is somehow incorrect in view of the utility of the scavenger receptor. Applicant is aware of no law supporting such a position. Applicant is also unaware of any utility standard requiring knowledge of the "true nature" of an invention, or any rule for determining what the "true nature" of an invention is. (See Office action at page 5, end of 2nd paragraph.)

Utility does not require perfection: "[t]he Federal Circuit has stated, '[t]o violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." M.P.E.P. § 2107.01 (underlining appears in the M.P.E.P.). Moreover, "courts have been reluctant to uphold a rejection under 35 U.S.C. § 101 solely on the basis that the Applicant's opinion as to the nature of the specific and substantial utility was inaccurate." M.P.E.P. § 2107.01. Applicant believes the asserted utility to be accurate, but even if it were to be inaccurate, such inaccuracy would not be sufficient grounds for a utility rejection.

The correct standard for judging utility is whether the claimed invention has a well-established utility, and failing that, whether the invention is specific, substantial, and credible. Because the claimed invention satisfies that standard, the claimed invention has a statutory acceptable utility and the rejection should be withdrawn.

B. THE CLAIMS ARE SUPPORTED BY A SPECIFIC, SUBSTANTIAL, AND CREDIBLE UTILITY AS WELL AS A WELL-ESTABLISHED UTILITY AS SET FORTH IN SPECIFICATION

The claimed invention has utility in accordance with both 35 U.S.C. § 101 and the Office's utility guidelines as it possesses a well-established utility as well as a specific, substantial and credible utility.

1. The Claimed Invention Has A Well-Established Utility

The claimed invention comprises a collectin and as such it possesses a well-established utility. The identification of the invention as a collectin is sufficient to establish utility under 35 U.S.C. § 101. Beginning on page 1 of the specification, the claimed polypeptide and polynucleotide is identified as a collectin, and the known, established properties of collectins are described, *e.g.*, anti-bacterial and anti-viral activity. *See, e.g.*, page 1, line 9, to page 2, line 16. Figure 5 shows the alignment of the claimed polypeptide with known collectins, see page 3, lines 23-25. "Courts have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound." M.P.E.P. § 2107.03.

As confirmation of Applicant's asserted utility, attached is a rule 132 declaration in which the inventor describes experiments that confirm the claimed invention has utility as set forth in the specification. The inventor showed that the claimed collectin is

able to bind to various saccharides (carbohydrate) in a calcium dependent manner, a property consistent with C-type lectins, including collectins. The collectin polypeptide was prepared and tested in its ability to bind various saccharides in the relative presence and absence of calcium. The results, summarized in the figure of paragraph 9, show that depletion of calcium ions with EDTA prevents the binding between the polypeptide and the saccharides tested. Accordingly the data discussed by the inventor confirm that the claimed polypeptide comprises a collectin and possesses utility(ies) associated with the same, and the rejection should be withdrawn.

Several of the publications of record also support the designation of the claimed subject matter as a collectin. For example, Hoppe and Reid (Ref. C30; Protein Science 3:1143-58 (1994)), describe the common structure of collectins (at pages 1144-1149), carbohydrate recognition (at pages 1149-1150) and binding of collectins to bacteria and viruses (at pages 1150-1152), and the Hoppe description is consistent with the collectin claimed in the present application and described in the specification.

Accordingly, because the claimed subject matter is a collectin and collectins have a well-established utility, the objection is improper and should be withdrawn.

2. The Claimed Invention Has A Specific, Substantial, and Credible Utility

The claimed invention has both a specific and substantial utility, and this utility is credible. To have a specific utility, the claimed species, *e.g.*, a protein, possesses a utility that is specific, *i.e.*, one not common to all proteins. The claimed species comprises a protein that binds saccharides in a calcium dependent manner. Not all proteins have such characteristics, which means the claimed species has a specific utility. The claimed species is also substantial. To be substantial, the claimed subject matter must have a "real world" use. The claimed collectin has utility as an anti-viral compound in the inhibition of infection. *See* pages 1 and 2 of the specification. To be credible, the utility must be believable to a person of ordinary skill in the art based on the totality of the evidence and the reasoning provided. The evidence and the reasoning provided establish that the claimed subject matter comprises a collectin and functions as such (see above discussion of the § 1.132 declaration as well as the support in literature of record). Accordingly, the rejection is improper and should be withdrawn.

V. THE CLAIMS FIND SUFFICIENT WRITTEN DESCRIPTIVE SUPPORT IN THE SPECIFICATION

A. THE SPECIFICATION TEACHES HOW TO USE THE CLAIMED INVENTION

On page 6 of the Office action, the Office rejected claims 97-155 under 35 U.S.C. § 112, first paragraph, as the invention was allegedly not supported by either a specific or substantial asserted utility or a well-established utility for the reasons described in relation to the § 101 rejection. Applicant respectfully traverses and submits that the rejection should be withdrawn for the same reasons as those described above in section IV.

B. THE CLAIMED SUBJECT MATTER IS ADEQUATELY DESCRIBED IN THE SPECIFICATION

On page 8 of the Office action, the Office rejected various claims under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant respectfully traverses.

The Office has failed to establish a *prima facie* case that Applicant has failed to provide proper written descriptive support or that Applicant has failed to provide a representative number of species. The Office asserted that Applicant failed to teach one particular species, that of the cited scavenger receptor. Applicant claims in the present application a genus as well as a number of species within that genus. If the standard were to require description of every species, comprising language would never be possible. Obviously, there is no such requirement under current U.S. practice. The present application does not have a claim directed specifically and exclusively to the scavenger receptor. Applicant does claim a scavenger receptor in co-owned U.S. Application No. 10/203,860, which would be comprised by present claim 156. Neither that co-pending application nor the references cited by the examiner undermine the written description of the present claims, because Applicant need not describe every species of a claimed genus.

Applicant teaches novel nucleic and amino acid sequences. The claimed polypeptides have utility (see above), *e.g.*, as antiviral agents, and the claimed polynucleotides encode these polypeptides. The claimed polynucleotides accordingly encode

polypeptides with utility and are not merely tools for obtaining a longer polynucleotide. Applicant has identified an open reading frame (ORF) that is sufficient to encode a polypeptide with the described properties, see specification at page 28, lines 23-28, and page 29, lines 26-28, and in accordance with the Written Description Guidelines (see following paragraph), is permitted to claim polynucleotides comprising a nucleic acid sequence comprising that ORF, polypeptides with amino acid sequences encoded by the same and polypeptides comprising such amino acid sequences.

The claims are not only supported by the specification, see Section II above, they are also consistent with Examples 9 and 14 of the Synopsis of Application Written Description Guidelines. The Office alleged that Example 9 is based on different facts as it is concerned with polynucleotides. However, Example 9 is only one example of the guidelines, and should not be interpreted in isolation. Example 14 specifically provides for claiming of polypeptide variants, based on a single described amino acid sequence, in combination with functional language specifying that the variants retain an activity of the polypeptide with the described amino acid sequence. The claimed polypeptides are consistent with this standard as they retain the ability to bind carbohydrates in a Ca^{2+}-dependent manner.

Accordingly, the claims have proper written descriptive support in the specification as filed, the rejection is improper, and the rejection should be withdrawn.

VI. THE CLAIMED HOST CELLS ARE ENABLED BY THE SPECIFICATION, AND THE REJECTIONS HAVE BEEN RENDERED MOOT

On page 6 of the Office action, the Office rejected claims 145-152 and 155 under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant respectfully traverses and submits that the rejection of claim 155 has been rendered moot in view of its cancellation and absence of any claim now pending that is directed to a transgenic mouse. The rejection of claim 155 should accordingly be withdrawn.

The Office objected to claims 145-152 as being directed to host cells that were not limited to isolated or *in vitro* cells because the claims allegedly read on a transgenic animal. Whether or not the claimed cells could read on cells within a transgenic animal described in the specification is immaterial to the analysis of whether the claimed host cells

are sufficiently enabled. Applicant is not presently claiming a transgenic animal, and it is improper to read limitations described in the specification into claims that do not recite such limitations. The claimed host cells do not become unpatentable or fall outside the scope of the claims simply because one should choose to administer them *in vivo*. Accordingly, the rejection is improper and should be withdrawn. Moreover, even if a transgenic animal were not described in the specification, the claims would still be enabled. Nevertheless, to expedite prosecution, claims directed to host cells now recite "isolated." Accordingly, the rejection has been rendered moot and should be withdrawn.

VII. THE CLAIMS ARE DEFINITE AND THE REJECTION HAS BEEN RENDERED MOOT

On page 11 of the Office action, the Office rejected claims 137-154 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Applicant submits that the rejection has been rendered moot by the cancellation of claims 137-154, and a similar rejection of the new pending claims would be improper. Accordingly, the rejection should be withdrawn.

VIII. THE APPLICATION HAS A PRIORITY DATE THAT ANTEDATES THE PUBLICATION DATE OF THE CITED REFERENCE AND IS ACCORDINGLY NOT ANTICIPATED BY THE SAME

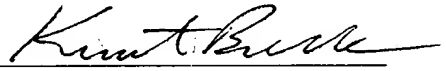
On page 12 of the Office action, the Office alleged that the claimed polynucleotides, vectors, host cells, probes, and methods were anticipated under 35 U.S.C. § 102(a) by WO 98/55614 (hereinafter '614). Specifically, the Office alleged that the sequence set forth in '614 comprised nucleotides 1-2019 of the nucleic acid sequence of SEQ ID NO: 1 of the present application. Applicant respectfully traverses and attaches the English translation of the priority document that the present application claims the benefit of (Exhibit A). The priority document was filed August 24, 1998, which precedes the publication date of December 10, 1998 of '614. SEQ ID NOS: 1 and 2 of the present application both appear in the priority document. Moreover, alignment of the '614 sequence and SEQ ID NO: 1 (see Exhibit B) reveals that the '614 sequence does not comprise nucleotides 1-2019, and actually has several differences. Accordingly, the rejection is improper and should be removed.

CONCLUSION

For the foregoing reasons, the Applicant respectfully submits that claims 156-219 are in condition for allowance. The Office is invited to contact the undersigned at the telephone number listed below in order to discuss any remaining issues or matters of form will move this case to allowance. A check covering the necessary fees is enclosed, and the attached transmittal forms authorize the Office to charge any additional fees to Applicant's account.

Dated: August 6, 2004

Respectfully submitted,

By 

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APPENDIX: SEQUENCE/CLAIM CHART

Relevant claims listed in order of polypeptides (e.g., 156-159), polynucleotides (e.g., 160-162, 218, 219), vectors (e.g., 198, 199) and host cells (e.g., 208, 209).

SEQ ID NO: 1 (nucleotides)	SEQ ID NO: 2 (amino acids)	RELEVANT TO NEW CLAIMS:	RELEVANT TO OLD CLAIMS:
739-1695	229-547	156-159 160-162, 218, 219 198, 199 208, 209	102-105, 107, 108 106, 107, 153, 154 138 146
730-1695	226-547	163-165 166, 167 200 210	97-99 100, 101 139 147
685-1695	211-547	168-170 171, 172 201 211	112-114 115, 116 140 148
670-1695	206-547	173-175 176, 177 202, 203 212, 213	109 110, 111 137 145
358-1695	102-547	178-180 181, 182 204 214	117-119 120, 121 141 149
325-1695	91-547	183-185 186, 187 205 215	122-124 125, 126 142 150
79-1695	9-547	188-190 191, 192 206 216	127-129 130, 131 143 151
55-1695	1-547	193-195 196, 197 207 217	132-134 135, 136 144 152